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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,695

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Friedbert Wechs

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EXAMINER

GONZALEZ, MADELINE

ART UNIT

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1778

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,695	<b>Applicant(s)</b> WECHS ET AL.	
	<b>Examiner</b> MADELINE GONZALEZ	<b>Art Unit</b> 1778	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 7-20 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7-9 and 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Claim Status**

Claims 1, 4, 5, 7-9 and 18-20 are rejected.

Claims 2, 3 and 6 have been cancelled.

Claims 10-17 are withdrawn.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities:

The limitation “the lumen” in line 17 lacks antecedent basis.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 5, 7-9 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation “wherein after prior drying” in line 21. This limitation is confusing because it is not clear what applicant means by “after prior”.

***Claim Rejections - 35 USC §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 5, 7-9, 19 and 20 are rejected under 35 U.S.C. 103(a) as obvious over Wang et al. (U.S. 6,565,782) [hereinafter Wang].

With respect to claims 1, 8, 9 and 19, Wang discloses membrane having:

- a hydrophilic, water-wettable membrane being based on;
  - a hydrophobic first polymer, such as polysulfone polymer (aromatic sulfone polymer) (see col. 5, lines 52-54); and
  - a hydrophilic second polymer such as polyvinylpyrrolidone (see col. 5, lines 54-55);
  - possessing an open-pored, integrally asymmetric structure across its wall, with a porous separating layer on its inner surface facing the lumen and an open-pored supporting layer (see col. 5, lines 31-38); and
  - whereby the membrane in the dry state is free from pore-stabilizing additives in the membrane wall (see col. 10, line 27 through col. 13, line 48).

Wang lacks the specific thickness of the separating layer, the specific ultrafiltration rate in albumin solution, the minimum sieving coefficient for cytochrome c

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and the maximum sieving coefficient for albumin. However, Wang teaches a membrane made of the same material as claimed by applicant and a similar process of making the membrane (see col. 10, line 27 through col. 13, line 48). It is therefore inherent that the membrane has the same ultrafiltration rate and sieving coefficients claimed by applicant, absent evidence to the contrary. Furthermore, it would have been obvious to obtain the specific ultrafiltration rate and sieving coefficients for the membrane disclosed by Wang since the court have held that “where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (*see In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)).

With respect to claim 4, Wang discloses wherein the aromatic sulfone polymer is polysulfone (see col. 5, lines 52-54).

With respect to claim 5, Wang discloses wherein the hydrophobic first polymer is a polysulfone or a polyethersulfone (see col. 5, lines 52-54).

With respect to claim 7, Wang discloses wherein the supporting layer extends from the separating layer across essentially the entire wall of the hollow-fiber membrane, has a sponge-like structure and is free from finger pores, as shown in Figs. 1C and 2A.

With respect to claim 20, Wang discloses wherein the supporting layer being essentially free from polyelectrolyte with negative free charges (see col. 10, line 27 through col. 13, line 48).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over a combination of Wang (U.S. 6,565,782) and Chu et al. (U.S. 4,604,208) [hereinafter Chu]

With respect to claim 18, Wang teaches that the membrane can be further modified by charge modification of the membrane surface in order to remove or exchange ions as a step in a filtration process (see col. 7, lines 27-37). Wang lacks a polyelectrolyte with negative fixed charges physically bound in the separating layer.

Chu teaches an anionic charge modified microporous membrane wherein a polyelectrolyte with negative charges is physically bound in the separating layer (see col. 9, lines 59-66) in order to enhance the filtration membrane performance of the membrane for charged particulate contaminants without decreasing the pore size of the membrane (see col. 5, lines 28-35). It would have been obvious to provide the membrane disclosed by Wang with a polyelectrolyte with negative fixed charges

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physically bound in the separating layer, as taught by Chu, in order to enhance the filtration membrane performance of the membrane for charged particulate contaminants without decreasing the pore size of the membrane (see col. 5, lines 28-35) and since Wang is already suggesting that the membrane can be further modified by charge modification of the membrane surface in order to remove or exchange ions as a step in a filtration process (see col. 7, lines 27-37).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 5, 7-9, and 18-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 14-16 and 18 of copending Application No. 10/588,016. Although the conflicting claims are not identical, they are not patentably distinct from each other because both disclose a hollow fiber membrane with polyelectrolyte bound in the separating layer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicant's arguments filed on March 18, 2010 have been fully considered but they are not persuasive.

In response to applicant's argument that Wang discloses membranes having pore size greater than 0.1 micron: It is noted that a pore size is not recited in the



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rejected claim(s) and therefore, this argument is not relevant to the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that Wang fails to come even close to disclosing the general conditions of Applicant's claim 1 and, therefore, it would have not being obvious to discover the optimum or workable ranges through routine experimentation: Wang teaches a membrane made of the same material as claimed by applicant, i.e., a hydrophobic first polymer, such as polysulfone polymer (aromatic sulfone polymer) (see col. 5, lines 52-54); and a hydrophilic second polymer such as polyvinylpyrrolidone (see col. 5, lines 54-55); possessing an open-pored, integrally asymmetric structure across its wall, with a porous separating layer on its inner surface facing the lumen and an open-pored supporting layer (see col. 5, lines 31-38); and whereby the membrane in the dry state is free from pore-stabilizing additives in the membrane wall (see col. 10, line 27 through col. 13, line 48). These are the general conditions of the membrane and are met by Wang, and therefore, it would have being obvious to discover the optimum or workable ranges through routine experimentation, as stated above.

In response to applicant's argument that Wang does not disclose membranes for hemodialysis, hemodiafiltration or hemofiltration, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior

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art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the membrane disclosed by Wang is capable of performing the intended use since Wang teaches that the membrane can be used in blood separation protocols (see col. 13, lines 38-45).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MADELINE GONZALEZ whose telephone number is (571)272-5502. The examiner can normally be reached on M, W, Th, F- 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/

Supervisory Patent Examiner, Art Unit 1778

Madeline Gonzalez

Patent Examiner

August 11, 2011